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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,676	10/31/2003	Martin T. Gerber	P0011666.00	1023

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EXAMINER	
KASZTEJNA, MATTHEW JOHN	

ART UNIT	PAPER NUMBER
3739	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No.	Applicant(s)	
	10/698,676	GERBER ET AL.	
	Examiner	Art Unit	
	MATTHEW J. KASZTEJNA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-36 and 38-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-36 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on February 22, 2008, amended claims 27 and 36 and canceled claims 37 and 46-47 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-24 of copending Application No. 10/698,213. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims involve an obvious broadening of the claims in application serial no. 10/698,676.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,486,161 to Lax et al.

In regards to claims 27, 30-32 and 34, Desai discloses a system for delivering a denervating agent to a prostate gland comprising: an imaging apparatus 302 sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole; a needle positioned through the hole of the imaging apparatus for insertion through a rectal wall of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen, wherein the needle is capable of extending out of the imaging apparatus parallel the long axis of the imaging apparatus (see Col. 19, Line 67 - Col. 20, Line 11 and Fig. 25). Furthermore, Desai discloses a method of localized fluid therapy (see Col. 19, line 57 – Col. 20, Line 51). Desai disclose an apparatus wherein a slidable portion 338 is responsible for extending and retracting a needle 306 into tissue but is silent with

respect to a spring-loaded needle and wherein actuating a spring mechanism to cause the distal end of the needle to be inserted into the prostate gland. Lax et al. teach of an analogous medical probe having a cutting cannula 84 which is spring-loaded in a retracted position and wherein a release tab 108 is pushed down to move the cannula forward when desired. It would have been obvious to one skilled in the art at the time the invention was made to include a spring-loaded needle in the apparatus of Desai to allow for more efficient and effective actuation of the needle into tissue as taught by Lax et al.

In regards to claims 28-29, Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the imaging apparatus comprises an ultrasonic imaging apparatus and is inherently capable of comprising a hyper-echoic coating as is well-known in the art (see Col. 19, Lines 64-67).

Claims 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,486,161 to Lax et al. in further view of U.S. Patent No. 6,365,164 to Schmidt.

In regards to claims 33 and 35, Desai and Lax et al. disclose a system for delivering a denervating agent to a prostate gland but are silent with respect to the denervating agent including botulinum toxin. Schmidt teaches methods for treating neuronally-mediated urologic and related disorders and more particularly, benign prostatic hyperplasia (BPH), by administering a composition that includes at least one neurotoxic compound. Such a neurotoxin can be botulinum toxin type A (see Col. 4, Lines 3-29). It would have been obvious to one skilled in the art at the time the

invention was made to use a composition including botulinum toxin type A with the device of Desai and Lax et al. in order to help more effectively treat BPH as taught by Schmidt.

Claims 36, 38-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,486,161 to Lax et al. in further view of U.S. Patent No. 7,037,294 to Luther et al.

In regards to claims 36 and 41, Desai discloses a system for delivering a denervating agent to a prostate gland comprising: an imaging apparatus 302 sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole; a needle positioned through the hole of the imaging apparatus for insertion through a rectal wall of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen, wherein the needle is capable of extending out of the imaging apparatus parallel the long axis of the imaging apparatus (see Col. 19, Line 67 - Col. 20, Line 11 and Fig. 25). Furthermore, Desai discloses a method of localized fluid therapy (see Col. 19, line 57 – Col. 20, Line 51). Desai disclose an apparatus wherein a slidable portion 338 is responsible for extending and retracting a needle 306 into tissue but is silent with respect to a spring-loaded needle and wherein actuating a spring mechanism to cause the distal end of the needle to be inserted into the prostate gland. Lax et al. teach of an analogous medical probe having a cutting cannula 84 which is spring-loaded in a retracted position and wherein a release tab 108 is pushed down to move the cannula

forward when desired. It would have been obvious to one skilled in the art at the time the invention was made to include a spring-loaded needle in the apparatus of Desai to allow for more efficient and effective actuation of the needle into tissue as taught by Lax et al. Desai and Lax et al. are silent with a wheel used to rotate the orientation of the needle. Luther et al disclose a needle having a wheel which permits rotation of the needle to a desired orientation. It would have been obvious to one skilled in the art to have further modified Desai and Lax et al. such that the spring-loaded needle includes a wheel to rotate the needle to a desired orientation. Such a modification allows to needle to be located more precisely in the target tissue as desired. The modified device of Desai and Lax et al. would be capable of permitting rotation of the needle while in the shaft.

In regards to claim 45, Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the imaging apparatus comprises an ultrasonic imaging apparatus and is inherently capable of comprising a hyper-echoic coating as is well-known in the art (see Col. 19, Lines 64-67).

In regards to claim 38, Desai discloses a system for delivering a denervating agent to a prostate gland, further comprising a denervating agent delivery 348 assembly coupled to the needle to deliver the denervating agent through the lumen (see Col. 17, Lines 18-57).

In regards to claims 39-40, Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery system assembly 348 includes a reservoir to hold the denervating agent and an actuator to

cause the denervating agent to flow from the reservoir through the lumen. As can be seen in Fig. 25 the second actuator comprises a plunger as well as a hub and a fluid line for attachment of the reservoir to the needle (see Col. 17, Lines 53-55).

In regards to claims 42-43, Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery assembly 348 includes a first reservoir to hold a substantial amount of the denervating agent, a second reservoir to hold a discrete dose of the denervating agent, and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator (see col. 20, Lines 51-65, and Col. 21, Lines 18-30). Syringe 348 is interpreted to be the first reservoir and the lumen of needle 306 is interpreted to be the second reservoir.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,486,161 to Lax et al. in further view of U.S. Patent No. 7,037,294 to Luther et al. in further view of U.S. Patent No. 6,365,164 to Schmidt.

In regards to claim 44, Desai, Lax et al. and Luther et al. disclose a system for delivering a denervating agent to a prostate gland but are silent with respect to the denervating agent including botulinum toxin. Schmidt teaches methods for treating neuronally-mediated urologic and related disorders and more particularly, benign prostatic hyperplasia (BPH), by administering a composition that includes at least one neurotoxic compound. Such a neurotoxin can be botulinum toxin type A (see Col. 4,

Lines 3-29). It would have been obvious to one skilled in the art at the time the invention was made to use a composition including botulinum toxin type A with the device of Desai, Lax et al. and Luther et al. in order to help more effectively treat BPH as taught by Schmidt.

Response to Arguments

Applicant's arguments filed February 22, 2008 have been fully considered but they are not persuasive.

With regard to method claims 27-35, and in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a method of delivering a denervating agent comprising rotating a wheel that permits rotation of the shaft relative to the handle while the shaft is inserted into the rectum) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As broadly as claimed, Desai disclose a method of using an apparatus wherein through the use of an endoscope, the user accurately position a probe near a site to be treated within the body (see Col. 19, line 57 – Col. 20, Line 51). Thus the shaft is rotated and moved with respect to the prostate gland and the combination of Desai and Lax et al. meet the limitations of the recited method claims.

In response to applicant's argument that Desai, Lax et al. and Luther et al fail to disclose an apparatus wherein a wheel permits rotation of the shaft relative to the

handle and while the shaft is inserted into the rectum, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

6/30/8